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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,295	01/22/2004	Joel A. Sequeira	AL0425KQ10	6543

24265 7590 10/06/2004

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

CLARDY, S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,295

Applicant(s)

SEQUEIRA ET AL.

Examiner

S. Mark Clardy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1 and 30-45 are pending in this application which is a continuation of application SN 10/426,329, now US Patent 6,723,713, which is a a continuation of US Application SN 10/050,396, now US Patent 6,677,322, which is a continuation of US Application SN 09/535,208, now US Patent 6,365,581, which is a continuation of SN 09/259,721, now US Patent 6,057,307, which is a continuation of SN 08/911,300, now US Patent 5,889,015, which is a continuation of both SN 08/821,135, now US Patent 5,837,699 (which is a continuation of SN 08/701,536), and SN 08/700,664, abandoned (which is a continuation of SN 08/444,582); both SN 08/701,536 and SN 08/444,582 are abandoned and are continuations of SN 08/376,506, abandoned, which is a CIP of SN 08/188,372, filed January 29, 1994, abandoned. Related application SN 10/763,143 is a continuation of the same parent patent.

Applicants' claims are drawn to a method of treating corticosteroid-responsive disease of the lower airway passages or lungs comprising once per day administration of 400 μ g of mometasone furoate from a dry powder inhaler.

In the '713 patent, the claims are drawn to a method of treating allergic rhinitis by administration of once daily 200 μ g of mometasone furoate (MF).

In the '322 patent, claims are drawn to a method of treating corticosteroid-responsive disease of the upper or lower airway passages or lungs comprising administration to surfaces of passages or lungs by inhalation from a dry powder inhaler of aerosolized particles of mometasone furoate at a dose of 25 to 1000 μ g.

In the '699 patent, the claims are drawn to methods of treating upper airway passages.

In the other parent patents, the independent claims further specify that the methods involve treating patients afflicted with such diseases, and use an amount of mometasone furoate

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which is effective for treating said diseases, but which is substantially non-systemically bioavailable.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 30-45 are provisionally rejected under the judicially created doctrine of double patenting over claims 1 and 30-38 of copending Application No. 10/763,143. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 1 and 30-45 are rejected under the judicially created doctrine of double patenting over the following claims of the following U. S. Patents, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Claims	US Patent/Application
1-10	6,723,713
1-14	6,677,323
1-15	6,677,322
1-25	6,365,581
1-29	6,057,307
1-35	5,889,015
1-21	5,837,699

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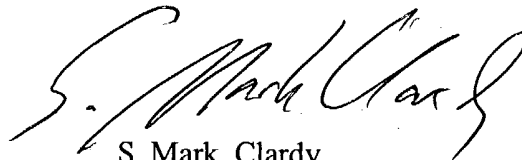
The subject matter claimed in the instant application is fully disclosed in the above patents and copending application and is covered by the patents since the patents and the instant application are claiming common subject matter, as follows: methods of treating corticosteroid-responsive diseases of airway passages and lungs by administration of mometasone furoate.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into patents. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Mark Clardy whose telephone number is 571-272-0611. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Mark Clardy
Primary Examiner
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September 30, 2004